



Recommendations for a National Medical Device Evaluation System from the National Medical Device Registries Task Force:

Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research

&

Aligning the Path Forward With the Planning Board Report

American College of Cardiology Heart House
Washington D.C.
Monday 24-August, 2015

8:00 - 8:30 AM

Registration & Continental Breakfast

8:30 - 8:40 AM

Welcome and Goals of the Day – Danica Marinac-Dabic, MD, PhD

8:40 - 9:00 AM

Medical Device Evaluation System: CDRH Vision of Needs & Challenges – Jeff Shuren MD, JD

9:00 - 10:30 AM

Recommendations of the MDRTF for a National Evaluation System

Panel/Moderator: Roberta Dressen, MBA

Introduction to Registries Task Force Report: Serving All Stakeholders With Better, Faster, Cheaper Medical Device Evaluation – Mitchell Krucoff, MD

- Infrastructure/CRN structure: priority areas and immediate & long term structure development: interoperability and dual purposing – Art Sedrakyan, MD, PhD
- Methodologic challenges & solutions – Sharon-Lise Normand, PhD
- Sustainability for TPLC: understanding the real value equation - actively creating a culture of good will & partnering – Eve Ross, JD
- Moderated Participant Question and Answer



10:30 - 10:40 AM Break

10:40 - 11:40 AM

Stakeholder Perspectives on the Registries Task Force Recommendations

Moderator: Fred Edwards, MD

- Experience of a Device Patient: What Could Be Better? – Anna McCollister-Slipp
- Registry-Based Device Evaluation: An Industry View of Needs & Challenges – Richard Kuntz, MD, MSc
- Perspective from Pew Charitable Trusts - Josh Rising, MD, MPH
- Moderated Participant Question and Answer

11:40 - 12:40 PM

Registries as an Integral Component of the Evolving National Medical Device Information Infrastructure

Moderator: Mark McClellan, MD, PhD

- Alignment with the Planning Board Recommendations for Medical Device Surveillance System – Greg Daniel, PhD, MPH
- Building blocks for patient centered research – Scott Smith, PhD
- Health IT: ONC and Interoperability – Julia Skapik, MD, MPH
- Moderated Participant Question and Answer

12:40 - 1:00 PM

Next steps & Adjournment

Mitch Krucoff, MD